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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/018,992

02/19/2003

Raffael Lahav

24305

2589

7590

07/03/2006

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EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/018,992		LAHAV ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Simon J. Oh		1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 40-91 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-91 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's response, petition for extension of time, and request for continued examination, all received on 06 June 2006.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear to the examiner how the recited enteric coating material can simultaneously have a neutral pH and a basic pH. Clarification is required.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 40-47 under 35 U.S.C. 103(a) over the combined disclosures of Heese *et al.* and Bergstrand *et al.* is hereby withdrawn.

The rejection of Claims 48-91 under 35 U.S.C. 103(a) over the combined disclosures of Heese *et al.* and Bergstrand *et al.* is maintained.

Claims 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiwe *et al.* (U.S. Patent No. 6,149,942)

The Scheiwe *et al.* patent teaches a pharmaceutical pellet formulation of omeprazole (See Abstract). The disclosed pharmaceutical formulation comprises a core containing the active agent (See Column 2, Lines 27-32). An enteric lacquer is then applied over the core. This coating layer can further comprise optional components, such as pH-adjusting agents (See Column 2, Lines 48-53). Suitable pH-adjusting agents include strong bases such as sodium hydroxide as well as buffering agents (See Column 3, Lines 15-18).

In the view of the examiner, the broad disclosure of the prior art makes the instantly claimed invention obvious. Despite the absence of an explicit disclosure of a neutral or basic pH of the enteric coating, one of ordinary skill in the art would be able to reasonably expect that an enteric coating layer comprising a sufficiently strong alkaline agent would have a neutral or basic pH. Thus, in the view of the examiner, the limitations of the instant claims have been met. Therefore, the instantly claimed invention is *prima facie* obvious.

### ***Response to Arguments***

Applicant's arguments filed 06 June 2006 have been fully considered but they are not persuasive.

In the view of the examiner, the open scope of Claims 48-91 still allow for the previous rejection over Heese *et al.* and Bergstrand *et al.* to stand. As stated previously, the composition described in the Heese *et al.* patent discloses a core coated with a polymer layer that is resistant

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to gastric acid, which is neutralized to a range of pH 5.5 to 7.0. Therefore, it has the functional properties of an enteric coating layer. In the view of the examiner, such a characterization reads on the limitations set forth in the instant claims, such that this polymer layer is not merely an intermediate coating layer, since the neutralized enteric coating layer is described almost entirely through functional limitations. Furthermore, there is no additional layer that exists between that neutralized enteric coating layer and the core. Despite the presence of yet another layer over this neutralized layer, the open scope of the claim language does not forbid the inclusion of such additional outer coating layers over the neutralized enteric coating layer. As such, the limitations of the claims, given their broadest reasonable interpretation, have been met by the disclosure of the prior art.

Previous arguments regarding 40-47 are now moot in view of the new grounds of rejection against those claims, detailed above.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh  
Examiner  
Art Unit 1618

sj0



MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER